



Instructions for Use

380290-C

English

For Veterinary Research Use Only

Store at 2-10 °C

VET-SAA 'Eiken' Reagent

REF V-SZ51

REF G-SZ52

INTENDED USE

For measurement of Serum Amyloid A (SAA) in animal serum or plasma.

* INTRODUCTION

Serum amyloid A (SAA) is an apolipoprotein associated in HDL. It has 11.4 kDa molecular weight and its amino acid sequence has high homology between animals. SAA has been considered as one of the most sensitive acute-phase protein as CRP. Serum SAA level rises dramatically by bacterial infection, viral infection, stress, trauma, inflammation, surgery, tumors, autoimmune diseases and tissue necrosis. Also, the level of SAA is considered to reflect healing of the inflammation. The increase occurs within 12hrs after induction and the level may increase 1000 times of normal concentration.^{1,2}

This measurement utilizes a latex agglutination reaction, and the change in turbidity caused by the reaction measured optically to determine SAA concentration.

PRINCIPLE OF THE METHOD

This method is an optical measurement method by using the latex agglutination reaction and automated analyzer.

The latex reagent is prepared by binding anti SAA antibodies to the surface of the latex particles. When this reagent is mixed in a react cell with the sample, SAA antibodies which are bounded to the latex particles react with SAA in the sample, and cause agglutination. This reaction is measured as a change in the turbidity, with the amount of the change increasing in proportion to SAA concentration in the sample.

Measurement using VET-SAA applies this principle to find a calibration curve from calibrators of known concentration. The amount of SAA in the sample is then found relative to this calibrator.

CONTENTS OF THE KIT

1. Reagent-1 20 mL, 2 vial
(Contains 50 mmol/L of Good's Buffer)
2. Reagent-2 20 mL, 2 vial
(Contains latex sensitized with anti SAA monoclonal antibodies)

WARNINGS AND PRECAUTIONS

1. For veterinary research use only.
2. Use the fresh animal serum or plasma. When samples are stored, they should be kept at -20 °C. Repeated freezing and thawing of sample should be avoided.
3. Be sure to store the reagents under the designated conditions(2-10 °C). Do not use reagents that have passed their expiration date.
4. Mix the latex reagent before using by gently inverting the vial several times.
5. Measurement errors may result if bubbles are present on the surface of the sample after it is dispensed into the sample cup. Therefore remove all bubbles. If fibrin is present in the sample cup, remove it. Fibrin can cause clogging of the sample nozzle.
6. Create a calibration curve for each day of measurement. Also be sure to create a new calibration curve when a reagent from a different vial or lot is used.
7. The test sample may be contaminated with pathogens. Therefore use caution when handling.
8. If the sample antigen concentration exceeds the measurement range, dilute with a normal saline solution or similar solution and perform measurement again.
9. Use the reagents as quickly as possible after they are opened. If they are to be stored, be sure to close the caps and store them using the prescribed method.
10. There is the danger of infection from all tools, reagents, and reagent containers that contact the sample. Disinfect them using an autoclave or other means, or soak them in hypochlorous acid or other disinfectant solution.
Example of treatment: Soak for 60 minutes or longer in a sodium hypochlorite solution (available chlorine concentration 1000 ppm or greater). (Neutralize any substances that contain acids before soaking.) Alternatively, treat in an autoclave at 121 °C for 20 minutes. (Do not treat in this way any items to which sodium hypochlorite has adhered.)
11. Dispose of used reagents, contents and containers as infectious waste in accordance with local regulations.
12. If the product is used in any way other than that specified here, the reliability of measurement results cannot be guaranteed. Be sure to follow the procedure.
13. The product contains Guanidinium chloride (CAS No.50-01-1, EC No.200-002-3), Lithium chloride (CAS No.7447-41-8, EC No.231-212-3), and ProClin300 (Mixture of 5-Chloro-2-methyl-4-isothiazolin-3-one and 2-Methyl-2H-isothiazol-3-one: CAS No.55965-84-9, EC No.911-418-6).
For details, see the box label.

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SAMPLE COLLECTION

1. Use animal serum or plasma as test sample (specimen).
2. Collect samples in usual manner and test them while fresh.
3. If test samples are to be stored over a long period of time, preserve them frozen at -20 °C or lower (avoid repeated freezing and thawing).
4. If a frozen stored test sample is to be used, thaw it at room temperature and then mix it by inversions before running the test.
5. Dialyzed blood-derived serum samples, in which fibrin is likely to be separated, should be defibrinated before used in the test.

TEST PROCEDURE

- * 1. Preparation of reagents
- 1) Reagent-1: Use the Reagent-1 as-is.
 - 2) Reagent-2: Use the Reagent-2 as-is.
 - 3) Calibrators: Separately obtain the VET-SAA Calibrator Set (REF V-SZ90 REF G-SZ93) as the calibrators.
2. Measurement procedure
- 1) Follow the instructions in the instruction manual to operate the automated analyzer.
 - 2) Dispense the sample and calibrators into sample cups, and set them in the designated positions.
 - 3) Set Reagent-1 and Reagent-2 in the designated positions.
 - 4) Enter the parameters into the analyzer.
 - 5) Press the analyzer "Start" key to begin analysis and output the measurement results (by printout or other means).

INTERFERING SUBSTANCES

Almost no effect on the measurement value was found from conjugated bilirubin (20 mg/dL), free bilirubin (20 mg/dL), hemoglobin (500 mg/dL), chyle (2,000 formazine turbidity units), and rheumatoid factor (RF positive sample 500 IU/mL). As an anticoagulant almost no effect on the measurement value was found from EDTA · 2Na (500 mg/dL), sodium citrate (1,000 mg/dL) and heparin sodium (40 mg/dL).

* INTERNAL QUALITY CONTROL

A quality control program to monitor the performance of VET-SAA is recommended to each laboratory. The following relevant products are being recommended for the quality control program.

VET-SAA-QC-Low (REF V-SZ91 REF G-SZ94)

VET-SAA-QC-High (REF V-SZ92 REF G-SZ95)

PERFORMANCE CHARACTERISTICS

1. Sensitivity
When measuring SAA calibrators of 0 mg/L and 7 mg/L, the average value -2.6SD of the absorbance change amount of 7 mg/L is larger than the average value +2.6SD of the absorbance change amount of 0 mg/L.
2. Accuracy
When control samples of known concentration were measured, the value obtained was within ±15 % of indicated value.
3. Within-run reproducibility
When the same sample was measured 10 times within the same run, the coefficient of variation (CV) for the values obtained was 10 % or less.
4. Measurement range
5 - 200 mg/L

* PRODUCT CODE, PRODUCT NAME & STORAGE

These products are stable until the expiration date on the label.

Product code	Product name	Contents	Storage
V-SZ51, G-SZ52	VET-SAA 'Eiken' Reagent	2 x 20 mL 2 x 20 mL	2-10 °C
V-SZ90, G-SZ93	VET-SAA Calibrator Set	5 x 1 mL	2-8 °C
V-SZ91, G-SZ94	VET-SAA-QC-Low	5 x 1 mL	2-8 °C
V-SZ92, G-SZ95	VET-SAA-QC-High	5 x 1 mL	2-8 °C

* REFERENCE

1. S. Jacobsen, P. H. Andersen The acute phase protein serum amyloid A (SAA) as a marker of inflammation in horses. *Equine vet. Educ.* 2007;19(1):38-46
2. Sack GH Jr. Serum amyloid A - a review *Mol Med.* 2018;24(1):46

* EXPLANATION OF SYMBOLS

	Batch code		Manufacturer
	Use by date		Temperature limitation
	Catalog number		Consult instructions for use



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